ATTACHMENT 35

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

- -x
SURGICAL INSTRUMENT SERVICE COMPANY, INC.,
Plaintiff,
-against-
INTUITIVE SURGICAL, INC.,
Defendant.
- -x

Virtual Zoom Deposition
March 10, 2023
9:00 a.m.

VIRTUAL VIDEO DEPOSITION of PHILIP J. PHILLIPS, in the above-entitled action, held at the above time and place, taken before Jeremy Richman, a Shorthand Reporter and Notary Public of the State of New York, pursuant to the Federal Rules of Civil Procedure, and stipulations between Counsel.

* * *

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made. They've issued a number of documents, including fellow legacy documents. 09:20:52 09:20:54 09:20:54

You mentioned the white paper. There's a draft guidance document. I view those as FDA statements as well as even requests that FDA reviewers have made of companies that I've looked at. 09:20:57 09:20:58 09:20:59 09:21:01 09:21:05 09:21:07

So I have considered those information, I considered those government statements. 09:21:09 09:21:11 09:21:13

Q. You did not review any statements by anyone at the FDA on the topic of extending the uses of EndoWrists; isn't that right, when you submitted this opening report? 09:21:15 09:21:18 09:21:19 09:21:21 09:21:24

A. I believe that that's correct. I mean, keep in mind, when I issued a rebuttal report, and I know we're not talking about the rebuttal report, I did look at some requests for additional information that came from FDA. 09:21:25 09:21:31 09:21:35 09:21:36 09:21:38 09:21:40 09:21:42

Q. What is that a reference to? 09:29:29

A. That was just simply FDA's 09:29:31
characterization of the product code 09:29:35
that was created for Intuitive's 09:29:36
surgical devices. 09:29:38

Q. Okay. Were you aware as of 09:29:40
December 2nd, 2022, that there was a 09:29:47
product code QSM for remanufactured 09:29:48
EndoWrists? 09:29:53

A. I don't know the answer to 09:29:57
your question. It could have been just 09:29:59
before the completion of my report or 09:30:02
just after, I do not know precisely. 09:30:04

Q. You did not view that product 09:30:08
code on the FDA website before you 09:30:09
submitted this report? 09:30:11

A. I believe that's correct. 09:30:14
But again, if there's no reference to 09:30:15
that product code in this document, 09:30:17
then the answer would be no, I did not. 09:30:20

Q. Do you think you learned 09:30:21
about it from the first time when you 09:30:24
read Ms. Foreman's report that she 09:30:25
submitted in this case? 09:30:32

product code for the one that Iconicare did, we're going to take the exact same thing, a monopole or a curved scissors, we're going to extend the lives, what is your recommendation for what regulatory pathway, if any, they would have to follow? 09:37:59 09:38:04 09:38:07 09:38:10 09:38:11 09:38:13 09:38:15

MR. MCCAULLEY: Objection to form. 09:38:16 09:38:17

A. Well, I believe that SIS would not be subject to much regulation because I would characterize their activities as servicing. I don't know what is the actual contents of the Iconicare 510(k). 09:38:17 09:38:19 09:38:21 09:38:23 09:38:26 09:38:28

So when you say they're doing what Iconicare is doing, I don't know what Iconicare actually presented to FDA and how that would actually impact my assessment. 09:38:30 09:38:33 09:38:35 09:38:37 09:38:41

Q. SIS tells you, it says this is what we're going to do. We're going to open up the EndoWrist, we're going to take off the chip that's there, 09:38:42 09:38:47 09:38:49 09:38:52

right, and then we're going to put on our own chip, right. You understand that's the basic process that Rebotix followed, right? 09:38:54 09:38:56 09:38:58 09:39:02

MR. MCCAULLEY: Objection to form. 09:39:02 09:39:04

A. Well, I understand what Rebotix followed and what SIS intended to follow. I don't know what Iconicare actually is doing or intended to do or what they described to the FDA. 09:39:04 09:39:06 09:39:08 09:39:12 09:39:16

Q. So it doesn't matter what they're doing, is that what you're saying? 09:39:18 09:39:19 09:39:22

A. No, it matters very much what they're doing. It's just that SIS is not doing what Iconicare was authorized to do. It's my understanding that SIS and Rebotix did not completely relabel their devices and offer them for sale in the open market. 09:39:22 09:39:24 09:39:27 09:39:31 09:39:33 09:39:36 09:39:39

Iconicare is perfectly free to do that. They have a 510(k) clearance for a device. Whether their 09:39:41 09:39:42 09:39:46

activity constitutes remanufacturing or servicing, I don't know exactly, because I've not seen the contents of their 510(k). But I do know what they are authorized to do based upon the order that FDA issued to them in connection with their 510(k) submission. 09:39:48 09:39:49 09:39:52 09:39:54 09:39:57 09:39:59 09:40:02 09:40:03

Q. In your work in this case from the beginning when you were engaged until today, have you seen any statement by any FDA official where they have characterized the extension of the lives of an EndoWrist as servicing? 09:40:04 09:40:13 09:40:16 09:40:19 09:40:22 09:40:24 09:40:27

A. No. 09:40:27

Q. Have you seen anywhere in all of the work that you've done in this case from the first day you were retained until today where any FDA official has characterized the extension of lives as repair? 09:40:34 09:40:38 09:40:41 09:40:42 09:40:45 09:40:46

A. No. 09:40:51

Q. You have seen that a number 09:40:51

A. Yes. 10:18:02

Q. Is it your understanding that the FDA created this product code for this particular device definition? 10:18:03 10:18:05 10:18:08

A. Yes. 10:18:10

Q. So as of some point in recently this was a new product code? 10:18:11 10:18:17

A. Yes. 10:18:20

Q. Do you know when it was created? 10:18:20 10:18:22

A. Well, it was in close proximity to the 510(k) clearance with Iconicare. 10:18:24 10:18:27 10:18:30

Q. And that was in September of 2022, correct? 10:18:31 10:18:34

A. Yes. I mean typically product codes are created very close to the actual clearance date and before clearance, but very close to the date. 10:18:35 10:18:37 10:18:39 10:18:42

Q. And this is -- what does it mean -- what does it mean in FDA world when they list a product code, what is the device definition mean? 10:18:44 10:18:47 10:18:53 10:18:55

A. It's just, again, in my 10:18:58

I believe that opinion is. 10:37:17

Q. Okay. And you tell them I am a hundred percent positive that this is a significant change, that's your opinion and you tell them I'm a hundred percent positive of that. 10:37:18 10:37:22 10:37:25 10:37:28 10:37:32

Are you with me? 10:37:34

A. Yes. 10:37:35

Q. And they say okay, what's that mean, Mr. Phillips, what's your response? 10:37:35 10:37:37 10:37:39

A. If you're 100 percent positive that it is a significant change that you made to the device, then you're likely a remanufacturer. 10:37:39 10:37:41 10:37:42 10:37:44

Q. And at that point you need to have a 510(k) before you can market your device, correct? 10:37:49 10:37:50 10:37:52

A. Well, again, depending on what the change is, 510(k) may or may not be appropriate. Most likely I would agree with you, 510(k) is appropriate, but there's a chance it's not. 10:37:53 10:37:59 10:38:04 10:38:06 10:38:07 10:38:09

Q. Meaning it could be a PMA? 10:38:09
A. Could be a PMA or it could be another de novo request, a de novo classification request. 10:38:11 10:38:13 10:38:16
Q. But they need some clearance from the FDA before they can market that device? 10:38:17 10:38:18 10:38:20
A. If they conclude that it is a significant change that they made to the device, the answer is yes. 10:38:21 10:38:23 10:38:25
Q. And then at that point they're subject to all the general controls of the device regulations, correct? 10:38:27 10:38:28 10:38:30 10:38:33
A. Yes. 10:38:33
Q. And they would have to relabel, right? 10:38:35 10:38:36
A. Yes. 10:38:43
Q. I mean after they get clearance from the FDA, they would have their own label, correct? 10:38:43 10:38:44 10:38:46
A. That is correct. Just like Iconicare did. 10:38:48 10:38:49
Q. Okay. Let's stay with this 10:38:50

510(k) clearances, very few. Because 510(k)s are generally cleared at lower levels within the organization. When things were brought to my attention, which was not the norm, then there was a higher likelihood that there could be some differences of opinion as to what the appropriate classification would be. 10:56:55 10:56:59 10:57:02 10:57:05 10:57:06 10:57:08 10:57:11 10:57:13 10:57:15

So on a whole, I didn't get involved very much. When I was involved in it and that's generally the review divisions coming to me for advice, then things could go either way. There were generally more complex situations that were under discussion. 10:57:16 10:57:18 10:57:21 10:57:22 10:57:24 10:57:27 10:57:30

Q. Are you familiar with the FDA guidance for medical device classification product codes? 10:57:31 10:57:33 10:57:35

A. No, not a guide specific to product codes, no. 10:57:37 10:57:44

MR. LAZEROW: I'm going to mark as DX, I think we're at 252 maybe, let me see, make sure I'm 10:57:45 10:57:47 10:57:54

Administration, document issued on April 11, 2013." 10:58:56 10:59:05

Do you see that? 10:59:06

(Exhibit 251, marked for identification, Medical Device Classification Product Codes, Guidance For Industry at Food and Drug Administration, document issued on April 11, 2013.) 10:59:08 10:59:08 10:59:08 10:59:08 10:59:09

A. Yes. 10:59:09

Q. And from your prior answer, I take it you haven't seen this before? 10:59:09 10:59:10

A. No. 10:59:12

Q. So you didn't view this in preparation of your rebuttal report? 10:59:12 10:59:14

A. No. 10:59:17

Q. What is your understanding of what a guidance represents from FDA? 10:59:17 10:59:21

A. Well, it's clear it explains what it does not represent, that it is an FDA requirement or it does not have the force of a regulation, so it's generally FDA expectations of a subject. 10:59:24 10:59:33 10:59:34 10:59:36 10:59:38 10:59:41

Q. Looking at DX251, do you have any reason to believe this is not a guidance that was issued by the FDA? 11:02:04 11:02:08 11:02:10

MR. MCCAULLEY: Objection to form, foundation. 11:02:15 11:02:16

A. Certainly appears to be a FDA guidance document. 11:02:17 11:02:19

Q. Okay, I'll represent I printed it, we printed it off the FDA website. But nonetheless, you're welcome to tell me, you know, it's not a guidance if you think it isn't. I'm on page, what is page 5, I don't think the numbers are numbered, so if we go to PDF page 5, let me see if that's where I want to be. Yes. 11:02:20 11:02:21 11:02:24 11:02:27 11:02:31 11:02:34 11:02:37 11:02:41 11:02:45

Go to PDF page 5 you'll see right in the middle it says: Premarket Notification 510(K) Devices. Do you see that? 11:02:46 11:02:49 11:02:51 11:02:52

A. Yes. 11:02:57

Q. And if you go down to C, Assignment. Do you see that? 11:02:57 11:03:00

A. Yes. 11:03:01

Q. On the sixth line there's a sentence all the way to the right that starts "However, if." Let me know when you're there. 11:03:01 11:03:07 11:03:09 11:03:11

A. I'm there. 11:03:11

Q. I'm sorry, I screwed up. Go one sentence before that, do you see the sentence that starts "A device"? 11:03:12 11:03:17 11:03:18

A. Yes. 11:03:21

Q. This guidance says "A device will be assigned an existing classification product code when it has the same intended use, indications for use, and relies on technology that does not raise new safety and effectiveness questions." 11:03:21 11:03:24 11:03:25 11:03:27 11:03:30 11:03:32 11:03:40

Do you see that? 11:03:40

A. Yes. 11:03:41

Q. "However, if the proposed device differs significantly from the predicate device with respect to technology, intended use or indications for use was not found substantially equivalent (NSE), a new product code 11:03:42 11:03:43 11:03:45 11:03:47 11:03:49 11:03:52

should be assigned." 11:03:58

Do you see that? 11:03:58

A. Yes. 11:03:59

Q. Is that your understanding as to when a new product code gets assigned? 11:03:59 11:04:01 11:04:03

MR. MCCAULLEY: Objection to form. 11:04:03 11:04:04

A. Yes, in general. I mean this is consistent with what I said before. A reviewer, a reviewer doesn't assign the product code, they have to work with an operations group to create a product code to be able to apply it in the SE letter. 11:04:04 11:04:06 11:04:07 11:04:12 11:04:14 11:04:15 11:04:18

So this isn't exactly precise, but reviewers, as I said before, it's the reviewer that determines the need for a new product code or the desire for a new product code. 11:04:20 11:04:22 11:04:23 11:04:25 11:04:27 11:04:29

Q. Does FDA do its best to follow its own guidances? 11:04:29 11:04:32

A. Usually. In this particular 11:04:34

moving through the process in the major deficiency section, FDA refers to the device as a remanufactured device. 11:10:28 11:10:30 11:10:33

Are you with me? 11:10:36

A. Okay. 11:10:37

Q. Okay. Does that change your opinion in this matter? 11:10:39 11:10:40

A. No. 11:10:43

Q. Okay. Is Christy Foreman an experienced regulatory professional? 11:10:43 11:10:48

A. Yes. 11:10:50

Q. And so are you absolutely stunned by the fact, by the facts you read in her report and her reliance on this product code? 11:10:51 11:10:56 11:10:59 11:11:03

A. I was a little surprised, perhaps. But again, you know, different people have different perspectives based upon their knowledge and experience at FDA. So it's not unusual to have experienced regulatory affairs people to have disagreements. 11:11:04 11:11:08 11:11:10 11:11:12 11:11:14 11:11:18 11:11:20

Q. So what you're saying is there's a chance she's right? 11:11:22 11:11:26

examples and not answering some of those examples, I think creates a tremendous amount of confusion. 11:51:03 11:51:05 11:51:08

Q. You're talking about the nondevice, nonspecific device example involving extending lives; is that what you're talking about? 11:51:09 11:51:11 11:51:15 11:51:17

A. Yes. 11:51:18

Q. Okay. And that was in 2018? 11:51:18

A. It was in the white paper, I believe it was 2018, yes. 11:51:21 11:51:23

Q. Right. And I want you to assume that every single time any FDA official has been presented with the question about whether extending the lives of EndoWrists is manufacturing -- remanufacturing or servicing, every single FDA official has said it's remanufacturing. 11:51:24 11:51:31 11:51:37 11:51:39 11:51:43 11:51:47 11:51:50 11:51:52

Can you assume that with me? 11:51:53

A. Yes. 11:51:55

Q. I want you to assume that this is the case from 2014 until today -- actually, I'll give it better. 11:51:56 11:51:58 11:52:01

Since the day da Vinci was on the market until today, every single FDA official and every single time the FDA is presented with that question, they said it's remanufacturing. 11:52:05 11:52:07 11:52:11 11:52:13 11:52:15

Are you with me? 11:52:17

A. Yes. 11:52:17

Q. Under my hypothetical, do you still believe, do you believe that there is ambiguity about whether that activity is remanufacturing? 11:52:17 11:52:19 11:52:21 11:52:23

A. Well, when you say "every individual," that means the Commissioner of FDA would weigh in on that same decision. 11:52:26 11:52:27 11:52:28 11:52:30

Q. No, every individual who was looked at it, every individual who has communicated with anyone in industry, who has done anything, anyone who has communicated, whether they sent a letter or copied a letter. 11:52:32 11:52:34 11:52:36 11:52:39 11:52:42 11:52:44

A. I think that there's a chance that the individuals could be wrong. 11:52:47 11:52:50

Q. What's your percentage chance 11:52:52

everything from that conversation that you are relying on for your opinions in this opening report? 13:33:21 13:33:24 13:33:27

A. Well, not necessarily for all of my opinions, but this was pivotal information that I wanted to glean from him what his intentions were and what his perspective was on these issues. 13:33:33 13:33:35 13:33:38 13:33:40 13:33:42

Q. Is there information that Mr. Posdal told you about their activities in this area that is not reflected in Paragraph 76 to 92? 13:33:44 13:33:48 13:33:53 13:33:55

A. I don't believe so. 13:34:01

Q. How long was the conversation? 13:34:02 13:34:06

A. I'm going to say maybe an hour, 45 minutes or so, I don't know exactly. 13:34:07 13:34:11 13:34:14

Q. Sorry, were you saying that it was one hour and 45 minutes? 13:34:14 13:34:16

A. No, I would say maybe 45 minutes, a half hour to 45 minutes is what I was thinking. It was relatively short. 13:34:18 13:34:21 13:34:25 13:34:27

Q. Did he suggest that you look at any documents? 13:36:21 13:36:23

A. I don't believe so. He was just answering the questions that I had prepared. 13:36:27 13:36:28 13:36:31

Q. Did -- was there anyone else involved in the conversation beside yourself? 13:36:31 13:36:33 13:36:36

A. Counsel was involved. And I think that that was, maybe, I don't remember it was Rick McCaulley or Stephen Sherry. There was counsel involved as well. 13:36:36 13:36:38 13:36:43 13:36:47 13:36:48

Q. No one else beside counsel and you and Mr. Posdal? 13:36:49 13:36:51

A. That's correct. 13:36:52

Q. Do you know if anyone recorded the conversation? 13:36:53 13:36:54

A. I do not know. 13:36:55

Q. One of the topics that was not discussed with Mr. Posdal was any efforts that SIS undertook to understand the applicable FDA regulatory requirements, right? 13:36:56 13:37:09 13:37:12 13:37:16 13:37:18

A. I don't believe I asked that question, correct. 13:37:20 13:37:23

Q. And he didn't provide you any information about what efforts, if any, that SIS had taken to understand the applicable regulatory requirements? 13:37:24 13:37:29 13:37:31 13:37:35

A. That really wasn't an interest of mine, it did not come up. 13:37:37 13:37:39

Q. Why not? 13:37:41

A. Well, I was doing an independent assessment of the situation. And I really wasn't looking for more of his perspective other than just a description of his activities and what his intent was. 13:37:42 13:37:46 13:37:47 13:37:50 13:37:52 13:37:54

Q. And so then when you submitted your report in this matter, you did not know what efforts, if any, SIS had taken to conform to applicable regulatory requirements, correct? 13:37:56 13:38:00 13:38:03 13:38:05 13:38:08

A. Yes, correct. 13:38:09

Q. Can you go into your box and find tab 31. You'll have it in your box also. If you rather work off 13:38:13 13:38:36 13:38:50

what it is that they're currently doing and maybe what it is that they desire to do. 14:12:14 14:12:16 14:12:18

Q. FDA looks at the activity that the entity is engaging in; isn't that right? 14:12:18 14:12:21 14:12:24

A. Yes, they do. 14:12:24

Q. FDA does not care what the intent of the company is with respect to how it determines whether a particular activity is servicing or remanufacturing, right? 14:12:27 14:12:30 14:12:31 14:12:35 14:12:37

A. Well, I believe that FDA just simply assumes that the intent aligns with whatever is included in the submission. 14:12:39 14:12:41 14:12:43 14:12:44

Q. Well, what if there's no submission and there's a company that's engaged in an activity that it believes is servicing, think about that situation, so there's been no 510(k) and FDA thinks it's remanufacturing, that the activity is remanufacturing. 14:12:45 14:12:48 14:12:50 14:12:55 14:12:57 14:12:59 14:13:04

Does it matter to FDA that 14:13:06

the company thinks it's servicing? 14:13:08

A. Yes, absolutely. 14:13:10

Q. Why? 14:13:11

A. Well, as I explained in one of my previous answers, before FDA draws any conclusions and draws, and considers enforcement actions, FDA virtually in all cases wants to know what the company's perspective is. If they believe that they are engaging in servicing activities, and they're not remanufacturing, and their changes are not significant changes, according to the remanufacturing definition, FDA would certainly want to know that. 14:13:13 14:13:15 14:13:18 14:13:20 14:13:23 14:13:27 14:13:28 14:13:30 14:13:31 14:13:34 14:13:36 14:13:38

Q. Right. But FDA would make the determination based on whether the activity are making significant changes, right? 14:13:40 14:13:41 14:13:44 14:13:50

A. FDA will review the application independent of whether the change is significant or not. 14:13:50 14:13:52 14:13:54

Q. Well, there's no application, so there's no application -- sorry, I 14:13:55 14:13:57

then and he does today. 15:08:39

Q. You can put that aside. 15:08:41

In your opening report you 15:08:52

reference the fact that Intuitive had 15:08:53

made changes to its own EndoWrist to 15:08:54

extend the number of lives without 15:09:02

going to the FDA to get a new 510(k). 15:09:03

Do you remember that? 15:09:05

A. Yes. 15:09:06

Q. And you did not -- were you 15:09:08

aware when you put that in your report, 15:09:12

were you aware that the FDA disagreed 15:09:14

with Intuitive, that they could follow 15:09:16

that pathway of not getting a new 15:09:22

510(k) clearance? 15:09:25

A. Yes. 15:09:26

Q. And are you aware that what 15:09:27

Intuitive did was they documented 15:09:30

within their files their decision 15:09:31

making around whether they needed to 15:09:34

get a 510(k)? 15:09:36

Are you aware of that? 15:09:37

A. Yes. 15:09:39

Q. Can you, you said your box 15:09:39

in Appendix C is provided as 30-50 minutes, compared to 20 minutes in the previously cleared labelling." 15:14:57 15:15:02 15:15:03

Do you see that? 15:15:05

A. Yes. 15:15:06

Q. So did you take this as FDA pointing out to Intuitive that the new filing has different number of uses and reprocessing cycles from the original device; is that right? 15:15:06 15:15:08 15:15:10 15:15:16 15:15:19

A. Yes. 15:15:22

Q. Okay. And it says, if you keep reading after E, you replied that "These changes were made between K173906 and the current submission without 510(k) clearance on the basis of FDA guidance deciding when to submit a 510(k) for a change to an existing device." 15:15:23 15:15:24 15:15:27 15:15:30 15:15:34 15:15:35 15:15:39 15:15:43

Do you see that? 15:15:43

A. Yes. 15:15:44

Q. And it continues and says "and internally documented nonfiling justifications." 15:15:45 15:15:48 15:15:53

Do you see that? 15:15:53

A. Yes. 15:15:53

Q. And so from this, do you take that what had happened with this particular submission is that Intuitive had documented in its files that pursuant to the guidance that is referenced there that it did not need a new 510(k) submission, right? 15:15:54 15:15:56 15:15:58 15:16:01 15:16:03 15:16:05 15:16:09

A. That was Intuitive's decision, yes. 15:16:11 15:16:12

Q. Right. FDA didn't agree with that, right? 15:16:13 15:16:15

A. That's what this suggests, yes. 15:16:16 15:16:18

Q. It says "However," if you keep reading, the last paragraph on this page, "However, we believe that changes to the reprocessing of your device require a 510(k). Your device falls under the endoscope and accessories regulation (21 CFR 876.1500). Per Appendix E of FDA's guidance reprocessing medical devices 15:16:18 15:16:20 15:16:22 15:16:23 15:16:25 15:16:29 15:16:31 15:16:38 15:16:41

but is not limited to items such as electrical safety, reprocessing, software and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition." 15:48:36 15:48:38 15:48:40 15:48:41 15:48:43 15:48:44 15:48:46 15:48:48 15:48:52 15:48:53 15:48:57 15:48:59

Do you see that? 15:49:00

A. Yes. 15:49:01

Q. I take it you did not review the document number CPT2000126 in the course of your work on this manner; is that right? 15:49:01 15:49:13 15:49:20 15:49:22

A. I don't believe I did. 15:49:22

Q. And do you have any reason to believe that Mr. Lee did not understand what it was that Rebotix Repair had disclosed to him about their activities? 15:49:23 15:49:25 15:49:30 15:49:34 15:49:35

A. Well, I don't know what Dr. Lee knew, but Dr. Lee doesn't have the authority to take any significant actions by way of a simple email. 15:49:36 15:49:41 15:49:44 15:49:45

Q. Does he have the authority to believe that the activities constitute remanufacturing? 15:49:49 15:49:50 15:49:51

A. Well, he can believe whatever he wants, but he doesn't necessarily represent the opinion of FDA. He may suggest that that's the case, but by corresponding informally by way of an email, that is not an appropriate way for FDA to cause any regulated entity to take any kind of a significant action. 15:49:52 15:49:54 15:49:56 15:50:00 15:50:03 15:50:05 15:50:06 15:50:10 15:50:11

Q. Well, he asked them to stop, right? 15:50:12 15:50:14

A. Yes. 15:50:14

Q. He didn't dictate that they have to stop, right? 15:50:15 15:50:18

A. I've had reviewers throughout the years request all kinds of things that upon any kind of a call or 15:50:19 15:50:21 15:50:24

servicing." 17:04:17
Do you see that? 17:04:17
A. Yes. 17:04:18
Q. You agree with that 17:04:18
statement, right? 17:04:19
A. Yes. 17:04:20
Q. The next sentence reads, 17:04:20
"Activities that are not intended to 17:04:22
significantly change the performance or 17:04:24
safety or specifications or intended 17:04:27
use of a device however, should still 17:04:30
be evaluated to determine whether the 17:04:34
change significantly affects device 17:04:36
performance and safety specifications 17:04:39
or intended use." 17:04:40
Do you see that? 17:04:41
A. Yes. 17:04:42
Q. Do you agree with that 17:04:42
statement? 17:04:45
A. I do. The regulation says 17:04:46
just significantly changes the device. 17:04:48
But I agree with this statement. 17:04:50
Q. Okay. So the focus when 17:04:52
you're trying to make this evaluation 17:04:54

is on whether the activities significantly affect the device performance and safety specifications or intended use, right? 17:04:56 17:04:59 17:05:02 17:05:03

A. Yes. 17:05:04

Q. The focus is not on whether the activities are intended to significantly change those items, right? 17:05:04 17:05:07 17:05:11 17:05:12

A. That's correct. 17:05:13

Q. You can put that one aside. 17:05:17

The -- I'm going all the way back to our first document together, which is your opening report. Do you have that in front of you? 17:05:24 17:05:28 17:05:29 17:05:34

A. Yes, I do. 17:05:39

Q. And I'm looking, when you have it, at page 1 of your report. 17:05:40 17:05:43

A. Yes. 17:05:50

Q. And page 1, I'm looking at Paragraph 4 and the end of Paragraph 4 it says "In particular"? 17:05:50 17:05:55 17:05:58

A. Yes. 17:05:59

Q. And there you lay out four 17:05:59

opinions that you hold in this matter, right? 17:06:03 17:06:07

A. Yes. 17:06:07

Q. And I'm looking at number 4, which is on the next page, it says "Intuitive Surgical's customer communications alleged in SIS's complaint and court filings are simply false and misleading." 17:06:08 17:06:11 17:06:14 17:06:16 17:06:19 17:06:21

Do you see that? 17:06:25

A. Yes. 17:06:26

Q. Now in arriving at that opinion, am I right, you did not review actual communications that FDA sent to customers, right? 17:06:26 17:06:32 17:06:34 17:06:37

A. That FDA sent to customers? 17:06:38

Q. I'm sorry. You did not review actual communications that Intuitive sent to customers? 17:06:41 17:06:42 17:06:45

A. I think it was from the complaint itself where these were alleged actions that Intuitive had taken. 17:06:47 17:06:48 17:06:50 17:06:53

Q. Okay. Did you ask to see the 17:06:53

actual communications? 17:06:56

A. I did not. I just went with 17:06:58
what was there assuming they were 17:07:01
factual. 17:07:03

Q. And if you turn to Paragraph 17:07:03
99 of this report. Are you there? 17:07:06

A. Yes, I am. 17:07:23

Q. It's on page 31? 17:07:23

A. Yes. 17:07:25

Q. Paragraph 99, just tell me if 17:07:25
I misunderstood what's here is you have 17:07:27
included allegations that were in SIS's 17:07:33
complaint and you've included, for 17:07:39
example, in their entirety with just 17:07:44
quoting directly from Paragraphs 123 17:07:46
through 125. 17:07:49

Do I understand that 17:07:51
correctly? 17:07:51

A. Yes. 17:07:52

Q. And then the next, at the end 17:07:52
of page 31, you cite to and quote from 17:07:57
other allegations in the complaint; is 17:08:04
that right? 17:08:06

A. That's correct. 17:08:06

Q. And you're writing on the next page from Paragraphs 97 through -- and 98; is that right? 17:08:07 17:08:08 17:08:13

A. Yes. 17:08:14

Q. And then the next, the last paragraph on page 32, you are quoting from Intuitive -- I'm sorry, from SIS's opposition to the -- to Intuitive's motion to dismiss, right? 17:08:14 17:08:20 17:08:23 17:08:28 17:08:31

A. Yes. 17:08:33

Q. Did you ask to see the actual communications that were sent to customers? 17:08:33 17:08:40 17:08:41

A. No. 17:08:42

Q. Did you do anything to verify that the allegations were -- in the complaint of SIS were correct? 17:08:43 17:08:47 17:08:49

A. Well, I assumed that there are communications between Intuitive and the hospitals or suppliers and that they must be making statements that relate to their position that the activities constitute remanufacturing and are illegal. 17:08:52 17:08:54 17:08:56 17:09:00 17:09:02 17:09:04 17:09:06

I disagree with that. I don't think that they are illegal. So any communications that would suggest that, I think are false or misleading. 17:09:08 17:09:09 17:09:11 17:09:12

Q. Are you taking issue with -- do you think it was false or misleading for Intuitive to tell customers, assuming they did, that the activity was remanufacturing? 17:09:15 17:09:19 17:09:20 17:09:22 17:09:25

A. Yes, I think that's improper. 17:09:27

Q. Was it false and misleading for Intuitive to tell customers that Intuitive viewed the activity as remanufacturing? 17:09:29 17:09:33 17:09:35 17:09:37

A. Well, I think it is false or misleading. Now that may be what Intuitive believes or wants to say. But the facts of this case make it very clear that no one knows what constitutes remanufacturing versus servicing. FDA has not clarified the issue, there's tremendous ambiguity about that. 17:09:40 17:09:44 17:09:48 17:09:49 17:09:52 17:09:53 17:09:55 17:10:00 17:10:03

So any communications that 17:10:03

would suggest that there has been some sort of interpretation I think is false or misleading under these circumstances. 17:10:05 17:10:07 17:10:09 17:10:10

Q. You would agree that experts may look at the specific issue of whether inserting a chip to reset the EndoWrist use counter is a significant change that would make SIS a remanufacturer, right? 17:10:11 17:10:13 17:10:15 17:10:18 17:10:21 17:10:27

A. They have, yes. 17:10:28

Q. Experts have come to different conclusions on that, right? 17:10:28 17:10:30

A. Yes. 17:10:31

Q. And so it's your view that even though experts come to different conclusions, Intuitive's not allowed to say its own belief to customers that this is actually remanufacturing? 17:10:32 17:10:36 17:10:37 17:10:40 17:10:46

A. Well, they're expressing their opinion. I mean, why are they expressing an opinion? They obviously want to communicate something and elicit some sort of a response. And to 17:10:47 17:10:49 17:10:50 17:10:52 17:10:53

statement, right? 17:17:10
A. Yes. 17:17:11
Q. And you think the definition 17:17:11
of remanufacturer in the QSR is not 17:17:12
clear, correct? 17:17:14
A. I don't believe it's clear 17:17:15
and as I state in Paragraph 11, I think 17:17:17
FDA admits that. 17:17:19
Q. And you believe, it's your 17:17:20
opinion in this matter that SIS's 17:17:24
activities were not remanufacturing, 17:17:29
right? 17:17:32
A. Correct. 17:17:33
Q. You've come to that 17:17:33
conclusion definitively, correct? 17:17:36
A. Yes. 17:17:38
Q. Zero doubt in your mind 17:17:38
whatsoever? 17:17:41
A. Correct. 17:17:41
Q. And now when someone 17:17:42
concludes that a particular activity, 17:17:45
that activity is remanufacturing, you 17:17:47
believe it's, that's so clear that it's 17:17:50
just wrong? 17:17:57

Q. In Paragraph 123 that you quoted from the SIS complaint. 17:21:05 17:21:06

A. Well, that's not coming from Intuitive, correct. 17:21:11 17:21:28

Q. Yeah, this is a quote that you lift directly from the SIS complaint? 17:21:28 17:21:30 17:21:32

A. From the complaint, yes. 17:21:32

Q. And my question to you is do you see anything in there where there is a direct quote allegedly from communication by Intuitive? 17:21:33 17:21:35 17:21:41 17:21:43

A. No, there's no level of detail that includes a specific complaint, no. 17:21:50 17:21:51 17:21:55

Q. And, in fact, Paragraph 123 doesn't even reference remanufacturing at all, correct? 17:21:56 17:21:58 17:22:00

A. That is correct. 17:22:01

Q. Paragraph 124, you don't see any reportedly direct quotes from communications by Intuitive to customers, correct? 17:22:03 17:22:07 17:22:10 17:22:12

A. That's correct, this is again 17:22:14

from the complaint, it's not Intuitive. 17:22:15

Q. And that paragraph does not reference remanufacturing, correct? 17:22:19 17:22:21

A. That is correct. 17:22:22

Q. And the same is true for Paragraph 125, you don't see in that paragraph from SI's complaint any purportedly direct quotes from Intuitive's communications to customers, correct? 17:22:25 17:22:27 17:22:30 17:22:33 17:22:35 17:22:36

A. Correct. 17:22:37

Q. And you don't see anything about remanufacturing in there, correct? 17:22:37 17:22:39 17:22:41

A. Correct. 17:22:42

Q. Okay. And looking at paragraph, the next page, you got, you'll see the quote mark is right before 97. Do you see that? 17:22:43 17:22:44 17:22:48 17:22:53

A. Yes. 17:22:54

Q. And I take it to mean you're quoting directly from Paragraph 97 of SIS's complaint. Did I read that correctly? 17:22:54 17:22:57 17:23:00 17:23:01

clear about this. 17:24:43

Q. You can't conclude if this was false or misleading just based on this little snippet, you would need more information. Is that fair to say? 17:24:48 17:24:50 17:24:50 17:24:52

A. I want to see the complete context, yes. 17:24:52 17:24:54

Q. Then it says, if you continue in that sentence, "SUCH that FDA and other regulations, quote, may not apply, end quote." 17:24:55 17:24:56 17:24:58 17:25:01

Do you see that? 17:25:02

A. Yes. 17:25:05

Q. And you would want more context around that little snippet, those three words that are purportedly quoted before you could determine whether that little quote there was false and misleading, right? 17:25:05 17:25:07 17:25:09 17:25:12 17:25:15 17:25:16

A. Well, again, I think in the context of what we're talking about, FDA has not clarified this situation to the point where anyone can draw conclusions about what, from a 17:25:17 17:25:19 17:25:21 17:25:23 17:25:25

regulatory perspective how this is going to be handled by the agency. 17:25:27 17:25:30

Q. And this -- sorry, were you done? 17:25:32 17:25:34

A. Yes. 17:25:35

Q. And this is saying exactly what you just said, right, the regulations may not apply, which by definition means they may apply, correct? 17:25:35 17:25:38 17:25:39 17:25:42 17:25:44

A. Yes, that's correct. But I think, again, the context in which these communications are being made, obviously, they're done for a particular purpose. What's Intuitive's purpose about communicating these? 17:25:46 17:25:48 17:25:51 17:25:54 17:25:55 17:25:57

Q. The next part of this sentence says "Intuitive states without any basis that, quote, the hospital has no way to know whether the refurbished instrument meets the rigorous specifications, end quote, of Intuitive and the FDA." 17:25:59 17:26:07 17:26:08 17:26:11 17:26:14 17:26:15 17:26:17

Do you see that? 17:26:18

A. Yes, let me just read that. Yes. What was your question? 17:26:20 17:26:35

Q. Just wanted to make sure you saw that. 17:26:37 17:26:38

A. Yes, I do see it. 17:26:38

Q. And you have no basis to say whether that statement is false or not, right? 17:26:40 17:26:45 17:26:48

A. That statement can be made within the context of all servicing operations, no matter what, whether they involve significant changes or not. I mean that's just the nature of servicing. 17:26:48 17:26:51 17:26:53 17:26:56 17:26:58 17:27:00

Q. Did you investigate in this matter whether hospitals had any way to know whether the refurbished instrument meets the specifications of Intuitive's EndoWrist? 17:27:00 17:27:02 17:27:06 17:27:09 17:27:12

A. No, I don't think they do, I think it's a truthful statement. What I'm saying is that any service organization that provides instruments to hospitals, hospitals cannot make 17:27:13 17:27:14 17:27:16 17:27:18 17:27:19

any usage limits for these types of devices. 17:29:47 17:29:51

Q. They've cleared the devices with the use limits that Intuitive had provided in their applications? 17:29:51 17:29:54 17:29:56

A. That's correct. 17:29:57

Q. So you don't see any quotes from, purported quotes from communications by Intuitive to customers in that Paragraph 98, right? 17:29:58 17:30:02 17:30:09 17:30:10

A. That's right, that is a characterization from the complaint, a SIS characterization from the complaint. 17:30:13 17:30:15 17:30:17 17:30:19

Q. And then if you look at the last paragraph which I think is, I cannot tell what it is, but it looks like you took it from the opposition to defendant's motion to dismiss. 17:30:19 17:30:21 17:30:27 17:30:29 17:30:31

Do you see that? 17:30:32

A. Yes. 17:30:33

Q. And SIS points to Intuitive Surgical letters to customers that say, for example, "The regulatory clearance 17:30:33 17:30:36 17:30:38